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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,952	01/02/2008	Takuji Kataoka	46884-5517 (232124)	6694
55694 7590 04/28/2011 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209			EXAMINER HANDY, DWAYNE K	
			ART UNIT 1773	PAPER NUMBER
			NOTIFICATION DATE 04/28/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBRIPDocket@dbr.com
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Office Action Summary	Application No. 10/594,952	Applicant(s) KATAOKA, TAKUJI	
	Examiner DWAYNE K. HANDY	Art Unit 1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 02/15/11 have been fully considered.
2. Applicant has deleted the previous apparatus claims. This is sufficient to remove the 102 rejections under Cottingham and Root (Paragraphs 3 and 4 of the previous Office Action). Applicant has provided new method claims (10-17) that recite the step of providing a masking member having an outer frame supporting the light shielding part. This is sufficient to overcome the previous 102 rejection under Krahn (Paragraph 5 of the previous Office Action). The Examiner has provided a new rejection below.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over He et al. (US 2003/0049862) in view of Krahn et al. (US 2002/022274). He teaches a biological assay device for analysis of molecules the embodiments of the device most relevant to the instant claims are shown in Figures 9A-10B and described in Paragraphs [0053] – [0057]. The assay device, as shown in the cited Figures, includes a container (well 1) and a permeable masking member with a light shielding part (side wall 24 / microcolumn 22 with disc 70) and outer frame part (support structure 10). The Examiner submits that providing the device of He having the container and masking member meets the step of preparing the light measuring kit (Step 1 of the instant method). In addition, He teaches use of their device in a wide variety of processes that includes the step of loading the well with sample material (instant Step 2). See Paragraphs 0054-0057.

Regarding the shielding step and measurement object placement step – The Examiner submits that the placement of the light shielding part over the container upper opening as shown in Figures 9B, 10A and 10B would shield material in the wells. He shows the addition of material into the well after the placement of the light shield part. The instant claims recite the shielding step after the measurement object addition/loading step. The Examiner takes the position that the difference between the prior art and these instant claims is an obvious change in the order of performing process steps that yields the same result. See MPEP 2144.04, Section IV, C. - "Changes in Sequence of Adding Ingredients". In this case, the shielding step of the prior art occurs before the addition of the measurement object and/or the addition of dye

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material but the end result is a shielded measurement object sandwiched between the masking member and container bottom. **He does not teach the dye addition step and does not teach optical analysis of the fluorescent dye.**

5. Krahn teaches a device and method for masking background fluorescence in optical analysis of cell samples. The method may include use of a separating layer (10) that also acts as a masking member to enhance the sensitivity and accuracy of the detection (Abstract). The analysis method is described in general in Paragraphs [0030] - [0031] and the claims. The method includes the steps of providing the container (1) with sample, adding the dye and reagent members, sandwiching the measured object(s) between the masking member and vessel bottom, and then measuring fluorescence (7). The embodiment of Krahn most relevant to the instant claims – having the permeable masking member (10) - is shown in Figures 6 and 7 and described in Paragraphs [0039] – [0042]. It would have been obvious to one of ordinary skill in the art to combine the dye reagents and optical features/steps from Krahn with the device of He. He teaches the purification and/or reaction of cell components into a well. One would add the dye reagents to assay the material in the well. One would add the masking layer material in order to take advantage of the improved optical properties provided by the masking layer as taught by Krahn (See Abstract and Paragraphs 0039 – 0041). One would analyze the material in the well using optical means to read the fluorescence assay results as in Krahn.

Regarding the shielding step and dye addition step – the Examiner submits that the placement of the light shielding part over the container upper opening as shown in

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Figures 9B, 10A and 10B would shield material in the wells. He shows the addition of material into the well after the placement of the light shield part. The instant claims recite the shielding step after the dye addition/loading step. The Examiner takes the position that the difference between the prior art and these instant claims is an obvious change in the order of performing process steps that yields the same result. See MPEP 2144.04, Section IV, C. - "Changes in Sequence of Adding Ingredients". In this case, the shielding step of the prior art occurs before the addition of the dye but the end result is a shielded assay mixture sandwiched between the masking member and container bottom.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DWAYNE K. HANDY whose telephone number is (571)272-1259. The examiner can normally be reached on M-F 11:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dwayne K Handy/
Examiner, Art Unit 1773

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1773

April 21, 2011